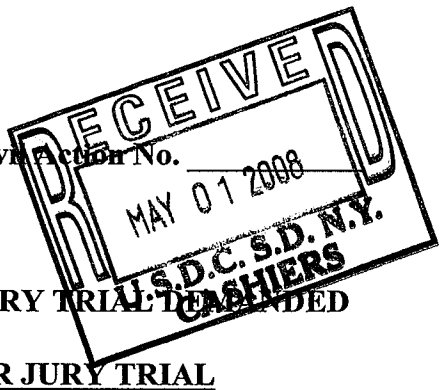
08 CIV 4177

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

SHAIL V. MEHTA,	§	
	§	
Plaintiff,	§	
	§	
v.	§	**Civil Action No.**
	§	
MERCK & COMPANY, INC.,	§	
	§	
Defendant.	§	**JURY TRIAL DEMANDED**



COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff Shail V. Mehta ("Plaintiff"), by and through her undersigned attorneys, sues Defendant Merck & Company, Inc., and alleges as follows:

I. JURISDICTION AND VENUE

1. This Court has jurisdiction pursuant to 28 U.S.C. § 132, as complete diversity exists between Plaintiff and Defendant. Plaintiff is a resident of the State of California and Defendant is incorporated and has its primary place of business in the State of New Jersey. The amount in controversy, exclusive of interest and costs, exceeds $75,000.00.

2. This Court also has jurisdiction pursuant to MDL 1789 Case Management Order No. 3, which allows for Plaintiff to directly file in the Southern District of New York.

3. Venue is proper within this district and division pursuant to 28 U.S.C. § 1391 and to MDL 1789 Case Management Order No. 3. Upon completion of all pretrial proceedings applicable to this case, this Court, pursuant to MDL 1789 Case Management Order No. 3, should transfer this case to the Santa Barbara County California Central District, pursuant to 28 U.S.C. § 1391, as a substantial number of events, actions, or omissions giving rise to the Plaintiff's claims occurred in that district. At all relevant times, Defendant conducted substantial business in that district.

II. PARTIES

4. At all relevant times, Plaintiff was a resident of Santa Barbara, California. Plaintiff used Fosamax from approximately April 2001 to June 2006, until he experienced oral and dental complications, including exposed bone.

5. Plaintiff brings this action individually to recover damages, restitution, refunds, and/or for equitable, injunctive and declaratory relief against Defendant.

6. Defendant is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's principal office is located at One Merck Drive, White House Station, New Jersey 08889-3400.

7. The Defendant's registered agent is CT Corporation System, and may be served at 111 Eighth Avenue, New York, New York 10011.

8. Defendant was at all times authorized to conduct business in the State of California.

9. Defendant has regularly transacted business in the State of California and continues to do so.

10. At all relevant times Defendant, through its agents, servants, employees, and apparent agents, was the designer, manufacturer, marketer, distributor and seller of Fosamax, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis, osteopenia, and Padget's Disease.

11. Defendant, either directly or through its agents, apparent agents, servants, or employees, at all relevant times sold, marketed, and distributed Fosamax in the State of California.

12. Defendant placed Fosamax into the stream of the worldwide commerce and interstate commerce in the United States. Defendant knew or should have known the serious side effects of Fosamax at the time that it marketed the drug to the public. Defendant did so without conducting adequate testing to establish the safety of Fosamax before marketing it. Rather, Defendant aggressively marketed Fosamax and promoted its use while downplaying evidence of the risk of a serious side effect — osteonecrosis of the jaws.

III. FACTUAL BACKGROUND

13. In September 1995, the United States Food & Drug Administration ("FDA") approved Defendant's compound Alendronate for various uses, including the treatment of osteoporosis and Paget's disease.

14. Alendronate's brand name is Fosamax. Defendant markets, distributes, and sells Alendronate as Fosamax. Fosamax has been widely promoted by Defendant as effective and safe.

15. Fosamax has been prescribed to millions of patients every year in the United States, and is sold throughout the world. Fosamax is one of Defendant's top selling drugs, averaging more than $3 billion a year in sales.

16. Fosamax is part of a class of drugs known as bisphosphonates. Bisphosphonates are used in treating bone conditions such as osteoporosis and Padget's disease. Other drugs in this class include Aredia and Zometa, which are used intravenously with cancer patients as chemotherapy and as adjunct chemotherapy.

17. There are two classes of bisphosphonates: the nitrogen containing and the non-nitrogen containing. Fosamax, like Aredia and Zometa, is a nitrogen containing bisphosphonate. The Physician's Desk Reference for Fosamax confirms that the compound contains nitrogen.

18. Because Fosamax contains nitrogen it accumulates in the bone and does not cleave or metabolize. Thus, Fosamax has an extremely long half-life (10 years).

19. Bisphosphonates, including Fosamax, inhibit bone formation, which in turn affects bone turnover and renewal, thus affecting bone re-absorption and remodeling.

20. Because jawbones remodel at a rate of 10 times the rate of other skeletal bones and have a greater uptake of bisphosphonates, bone re-absorption and remodeling is more significantly affected by the ingestion of Fosamax. Thus, as the demand for remodeling occurs or if trauma, such as tooth removal or deep cleaning, occurs, jawbones can no longer respond by forming new bone and become necrotic. This is called osteonecrosis of the jaws.

21. Osteonecrosis of the jaws is a rare disease. It is disfiguring and disabling. Osteonecrosis of the jaws is a condition characterized by exposed necrotic (dead) bone in the mandible or maxilla. The necrotic bone is non-healing. There is a high incidence of infection, which can lead to osteomyelitis and infected jawbones. The disease process can progress to a point where either necrotic bone detaches from the jaws leading to sequestration of bone or can require sections of the necrotic bone to be surgically removed. Osteonecrosis of the jaws is difficult to treat and is typically irreversible.

22. For years since Defendant began selling, marketing, and distributing Fosamax, physicians and dentists have acknowledged the observed risk of osteonecrosis of the jaws caused by the use of the intravenous bisphosphonates, Aredia and Zometa.

23. Since the late 1990's, medical articles and studies linked the use of the nitrogenous bisphosphonates for chemotherapy with osteonecrosis of the jaws.

24. In November 2003, the FDA's Office of Drug Safety ("ODS") completed a consult regarding osteonecrosis of the jaws associated with the intravenous bisphosphonates.

The ODS concluded that there was a safety concern with intravenous bisphosphonates and that labeling should be amended to include that osteonecrosis of the jaws is associated with these medications. Further, there was a need to review oral bisphosphonates like Fosamax, to determine if osteonecrosis of the jaws is a class wide effect.

25. In 2005, several studies were published that confirmed the significance of the disease and confirmed the causal link between osteonecrosis of the jaws and the use of intravenous nitrogenous bisphosphonates.

26. Defendant, knowing that Fosamax was a nitrogen containing bisphosphonate, knew or should have known that Fosamax shared the same risks as Aredia and Zometa, the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study regarding the risk of osteonecrosis of the jaws relative to Fosamax. Further, despite knowledge of this class effect, Defendant failed to warn of the risk of osteonecrosis of the jaws.

27. Since its November 2003 consult, the FDA continued to receive reports of osteonecrosis of the jaws and other dental complications among users of bisphosphonates, including Fosamax. This prompted the FDA's ODS to conduct an epidemiological review of the FDA's adverse events database. The ODS focused on Aredia, Zometa, Actonel, and Fosamax — all nitrogenous bisphosphonates — to determine if osteonecrosis of the jaws was a class wide effect.

28. As a result of the ODS's review, it issued a Post Marketing Safety Review of bisphosphonates in August 2004 concluding that the risk of osteonecrosis of the jaws was not only confined to intravenous bisphosphonate use, but was a class wide event.

29. Based on this finding, the FDA indicated a need for changes to the product labels, including Fosamax's label, to specifically warn about the risk of osteonecrosis of the jaws.

30. Defendants failed to make the necessary changes to Fosamax's product label. Rather than warn the patients and physicians, Defendant continues to intentionally mislead patients, physicians and the public by defending Fosamax and minimizing unfavorable press and findings.

31. Since approving Fosamax, the FDA has admonished Defendant several times for overstating the benefits of Fosamax and minimizing the risks in its marketing materials. Despite these admonishments, Defendant has not changed its pattern of behavior.

32. In fact, rather than evaluating the safety of Fosamax, Defendant sought to extend the use of its product by manufacturing, marketing, selling, and distributing Fosamax-D. Defendants also sought to extend the exclusivity period of Fosamax through 2018.

33. Defendant knew or should have known about the significant risks of dental and oral and dental complications, including osteonecrosis of the jaws, caused by the ingestion of Fosamax. Despite this knowledge, Defendant did not adequately or sufficiently warn consumers, including Plaintiff, or the medical community of such risks.

34. As a direct result of Defendant's conduct, Plaintiff was prescribed Fosamax from April 2001 to June 2006. Plaintiff used Fosamax as prescribed and in a foreseeable manner.

35. As a direct and proximate result of ingesting Fosamax, Plaintiff has been permanently and severely injured. Plaintiff requires and will in the future require ongoing medical and dental care and treatment.

IV. CAUSES OF ACTION

COUNT 1: NEGLIGENCE

36. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

37. Defendant had a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, selling, and/or distributing Fosamax into the stream of commerce. Defendant had a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects and harm.

38. Defendant failed to exercise ordinary care in the design, manufacture, marketing, advertising, testing, quality assurance, quality control, sale and/or distribution of Fosamax into the stream of commerce.

39. Defendant was negligent in the design, marketing, manufacture, testing, advertising, warning, sale and/or distribution of Fosamax in that it:

a. Failed to use due care in designing Fosamax so as to avoid the oral and dental complications and side effects, including osteonecrosis of the jaws;

b. Failed to accompany Fosamax with proper warnings regarding all possible side effects associated with the use of Fosamax;

c. Failed to properly and thoroughly conduct adequate pre-clinical testing of Fosamax before releasing the drug to the market;

d. Failed to properly and thoroughly analyze the data resulting from the pre-marketing test of Fosamax;

e. Failed to conduct sufficient post-market testing and surveillance and/or medical monitoring to determine the safety of Fosamax;

f. Failed to accompany Fosamax with adequate warnings of the significant and dangerous risks and failed to provide proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

g. Failed to exercise due care when advertising and promoting Fosamax;

h. Failed to provide adequate training and/or information to health care professionals for appropriate use of Fosamax; and

i. Failed to warn that the dangers and risks associated with Fosamax could exceed other comparable treatments for osteoporosis.

40. Despite the fact that Defendant knew or should have known that Fosamax caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, Defendant continued and still continues to market Fosamax to consumers, including Plaintiff, when there were safer alternative methods for the treatment of osteoporosis.

41. Defendant knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care as described above.

42. Likewise, Defendant was negligent in seeking approval, marketing and selling Fosamax-D, given Defendant's knowledge of the dangers associated with Fosamax, nitrogenous bisphosphonates.

43. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

44. As a direct and proximate consequence of Defendant's conduct, Plaintiff sustained oral and dental complications and exposed bone. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of pre-existing conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care

for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

COUNT 2: STRICT LIABILITY — DESIGN DEFECT

45. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

46. At all times material to this lawsuit, Defendant manufactured Fosamax.

47. At all times material to this lawsuit, Defendant was engaged in the business of distributing and selling Fosamax.

48. Defendant sold the Fosamax, which was ingested by Plaintiff, as alleged in this Complaint.

49. Plaintiff ingested Fosamax which was expected to reach the user without substantial change in the condition in which it was sold.

50. Plaintiff ingested Fosamax which reached her without substantial change in the condition in which it was sold.

51. Plaintiff was a person who would reasonably be expected to use Fosamax.

52. Fosamax was defective and, because of its defects, was unreasonably dangerous to persons who might reasonably be expected to require its use. In addition, this drug was dangerous to the extent beyond that which could reasonably be contemplated by Plaintiff, and any benefit of this drug was far outweighed by the serious and undisclosed risks of its use.

53. The Fosamax manufactured and/or supplied by Defendant was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with its design or formulation.

54. Despite the fact that Defendant knew or should have known that Fosamax caused unreasonable and dangerous side effects, which users would be unable to avoid by any means, they continued to promote and market Fosamax when there existed safer and more effective alternative drug products.

55. Fosamax was defective at the time it was distributed by the Defendants or left its control.

56. The defects in the Fosamax ingested by Plaintiff were a direct and proximate cause of the injuries and damages sustained by Plaintiff as set forth in this Complaint.

57. As a direct and proximate consequence of Defendant's conduct, Plaintiff sustained oral and dental complications and exposed bone. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of pre-existing conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

COUNT 3: STRICT LIABILITY — MARKETING DEFECT — FAILURE TO WARN

58. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further allege as follows:

59. At all times material to this lawsuit, Defendants manufactured Fosamax.

60. At all times material to this lawsuit, Defendants were engaged in the business of distributing and selling Fosamax.

61. Defendants sold the Fosamax, which was ingested by Plaintiff, as alleged in this Complaint.

62. Plaintiff ingested Fosamax which was expected to reach the user without substantial change in the condition in which it was sold.

63. Plaintiff ingested Fosamax which reached her without substantial change in the condition in which it was sold.

64. Plaintiff was a person who would reasonably be expected to use Fosamax.

65. Fosamax is unreasonably dangerous, even when used for its intended purpose.

66. Defendant, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Defendant had knowledge of the dangerous risks of Fosamax.

67. Plaintiff did not have the same knowledge as Defendant and no adequate warning was communicated to Plaintiff or her physician.

68. Defendant had a continuing duty to warn consumers and physicians, including Plaintiff and Plaintiff's physicians, of the risks and dangers associated with Fosamax.

69. Defendant marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Fosamax, to health care providers empowered to prescribe and dispense Fosamax to consumers, including Plaintiff, without adequate warning and misled the medical community about the risk/benefit balance of Fosamax, which resulted in injury to Plaintiff.

70. Despite the fact that Defendant knew or should have known that Fosamax caused unreasonable and dangerous side effects, which users would be unable to avoid by any means,

they continued to promote and market Fosamax when there existed safer and more effective alternative drug products.

71. Defendant knew or should have known that consumers, including Plaintiff, would foreseeably and needlessly suffer injury as a result of the Defendant's failure to warn.

72. Defendant failed to provide timely and adequate warnings to physicians, distributors, and consumers, including Plaintiff and her physician, in the following ways:

a. Failed to include adequate warnings with the medications that would alert Plaintiff and Plaintiff's physician to the dangerous risks of Fosamax;

b. Failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, osteonecrosis of the jaws; and

c. Continued to aggressively promote Fosamax, even after Defendant knew or should have known of the risks of injury from this drug.

73. By failing to warn Plaintiff and Plaintiff's physician of the adverse health risks associated with Fosamax, Defendant breached their duty to Plaintiff of reasonable care and safety.

74. As a direct and proximate consequence of Defendant's conduct, Plaintiff sustained oral and dental complications and exposed bone. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of pre-existing conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care

for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

75. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damage so as to punish Defendant and deter it from similar conduct in the future.

COUNT 4: BREACH OF EXPRESS WARRANTY

76. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

77. Defendant expressly represented to Plaintiff and other consumers in the medical community that Fosamax was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

78. Fosamax does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

79. At all relevant times Fosamax did not perform as safely as ordinary consumers would expect when used as intended or in a reasonably foreseeable manner.

80. Plaintiff, other consumers, and the medical community relied upon Defendant's express warranties.

81. As a direct and proximate consequence of Defendant's conduct, Plaintiff sustained oral and dental complications and exposed bone. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life,

increased risk of premature death, aggravation of pre-existing conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

82. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT 5: BREACH OF IMPLIED WARRANTY

83. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

84. Defendant manufactured, distributed, advertised, promoted and sold Fosamax.

85. At all relevant times, Defendant knew of the use for which Fosamax was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

86. Defendant was aware that consumers, including Plaintiff, would use Fosamax for treatment of osteoporosis and for other purposes. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Defendant to sell Fosamax only if it was indeed of merchantable quality and safe and fit for its intended use.

87. Defendant breached its implied warranty to consumers, including Plaintiff. Fosamax was not of merchantable quality or safe and fit for its intended use.

88. Consumers, including Plaintiff and the medical community, reasonably relied upon Defendant's implied warranty for Fosamax.

89. Fosamax reached consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

90. As a direct and proximate consequence of Defendant's conduct, Plaintiff sustained oral and dental complications and exposed bone. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of pre-existing conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

91. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT 6: FRAUDULENT MISREPRESENTATION

92. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

93. Defendant made fraudulent misrepresentations with respect to Fosamax in the following particulars:

a. Defendant represented through its labeling, advertising, marketing, materials, detail persons, seminar presentations, publications, notice letters and regulatory submissions that Fosamax had been tested and found to be safe and effective for the treatment of pain and inflammation; and

b. Defendant represented that Fosamax was safer than other alternative medications.

94. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of Fosamax to consumers, including Plaintiff, and the medical community.

95. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, would rely upon them.

96. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, the medical community, and to induce and encourage the sale of Fosamax.

97. Plaintiff, Plaintiff's doctors, and others relied upon the representations.

98. Defendant's fraudulent representations evidence its callous, reckless, willful, and depraved indifference to health, safety, and welfare of consumers, including Plaintiff.

99. As a direct and proximate consequence of Defendant's conduct, Plaintiff sustained oral and dental complications and exposed bone. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of pre-existing conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

100. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of

consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT 7: FRAUDULENT CONCEALMENT

101. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

102. Defendant fraudulently concealed information with respect to Fosamax in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters and regulatory submissions that Fosamax was safe and fraudulently withheld and concealed information about the substantial risk of use of Fosamax; and

b. Defendant represented that Fosamax was safer than other alternative medications and fraudulently concealed information which demonstrated that Fosamax was not safer than alternatives available on the market.

103. Defendant had sole access to material facts concerning the dangers and unreasonableness of Fosamax.

104. The concealment of information by Defendant about the risks of Fosamax was intentional, and the representations made by Defendant were known by Defendant to be false.

105. The concealment of information and the misrepresentations about Fosamax were made by Defendant with the intent that doctors and patients, including Plaintiff, would rely upon them.

106. Plaintiff, Plaintiff's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks of Fosamax which Defendant concealed from Plaintiff and the medical community.

107. As a direct and proximate consequence of Defendant's conduct, Plaintiff sustained oral and dental complications and exposed bone. In addition, Plaintiff required and will continue to require dental and medical care and treatment. Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of pre-existing conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

108. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT 8: PUNITIVE DAMAGES

109. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

110. Defendant has repeatedly engaged in a pattern of conduct of deliberately misleading consumers and the medical community of the risks and benefits associated with Fosamax.

111. Defendant has been repeatedly admonished by the FDA for marketing and promotional materials that were in violation of the Federal Food, Drug, and Cosmetic Act. Since 1995, the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC")

issued several letters to Defendant identifying various misleading marketing and promotional materials.

112. In August of 1997, the DDMAC informed Defendant that its "Compare the Facts" Flashcard was misleading because it failed to present important risk information for Fosamax and lacked a fair balance of the risks and benefits. Further, the Flashcard was misleading because it implied that Fosamax's efficacy was superior to other treatments despite the lack of data. The brochure also overstated the population of women eligible for therapy with Fosamax.

113. The DDMAC informed Defendant of another violation in August of 1997. Defendant was put on notice of several violations regarding a Fosamax brochure, reprint holder, slide presentation and journal ad. The FDA concluded that all of the materials were misleading because the Defendant failed to present important risk factors, failed to present a fair balance presentation of risk information and efficacy, and overstated the efficacy of Fosamax as related to fracture incidence. Overall, the FDA requested Defendant to discontinue the dissemination of the misleading materials.

114. Again in 1999, Defendant was requested to discontinue the use of certain promotional materials for Fosamax because it failed to include risk information or a summary of necessary information related to side effects.

115. In 2000 and 2001, the DDMAC issued yet another admonishment regarding Defendant's Fosamax web site which overstated the potential benefit of Fosamax while down playing the risks and serious adverse effects associated with Fosamax.

116. Despite these repeated admonishments by the FDA, Defendant has engaged in the same pattern of conduct. Defendant continues to mislead the consumers and medical community

by working to defend Fosamax and minimize the risk of osteonecrosis of the jaws in its promotional materials.

117. Defendant has also repeatedly engaged in the pattern of conduct of deliberately avoiding the FDA's recommendations regarding which risks associated with Defendant's drugs should be warned about.

118. In November 2003, the FDA's Office of Drug Safety ("ODS") completed a consult regarding osteonecrosis of the jaws associated with the intravenous bisphosphonates. The ODS concluded that labeling should be amended to include that osteonecrosis of the jaws is associated with these medications. Further, the ODS stated that there was a need to review oral bisphosphonates like Fosamax, to determine if osteonecrosis of the jaws is a class wide effect.

119. After its November 2003 consult, the ODS conducted an epidemiological review of the FDA's adverse events database. The ODS focused on Aredia, Zometa, Actonel, and Fosamax — all nitrogenous bisphosphonates — to determine if osteonecrosis of the jaws was a class wide effect. As a result of this review, the FDA issued a Post Marketing Safety Review of bisphosphonates in August 2004 concluding that the risk of osteonecrosis of the jaws was not only confined to intravenous bisphosphonate use, but was a class wide event. Thus, the FDA indicated a need for changes to the product labels, including Fosamax's label, to specifically warn about the risk of osteonecrosis of the jaws.

120. Despite, the August 2004 FDA's indication to change the Fosamax label and to warn of osteonecrosis of the jaws, Defendant has failed to do so. Rather than warn the patients and physicians, Defendant continues to intentionally mislead patients, physicians and the public by defending Fosamax and minimizing unfavorable press and findings.

121. Defendant's disregard of the FDA's recommendations has not only occurred with its drug Fosamax, but also with its drug Vioxx.

122. In March 2000, Defendant completed a study called VIGOR (Vioxx Gastrointestinal Outcome Research) relating to its prescription Cox-II inhibitor, Vioxx. The VIGOR study showed that Vioxx patients had more than doubled the rate of serious cardiovascular problems than those on Naproxen, an older non-steroidal anti-inflammatory drug. The study was published in the New England Journal of Medicine.

123. In September 2001, the FDA admonished Defendant to stop misleading consumers and the medical community about Vioxx's effects on the cardiovascular system and minimizing the risks of the drug in its marketing. Like with Fosamax and osteonecrosis of the jaws, Defendant refused to adequately warn consumers and the medical community about the risks of heart attacks and Vioxx.

124. On August 25, 2004, a representative from the FDA presented results of a database analysis of 1.4 million patients. The analysis demonstrated that Vioxx users were more likely to suffer a heart attack or sudden cardiac death than those taking Celebrex or other non-steroidal drugs. The FDA representative concluded that Vioxx was linked to more than 2,700 heart attacks or sudden cardiac deaths nationwide from the time it came on the market in 1999 through 2003.

125. Defendant worked to defend Vioxx, much like it is doing now with Fosamax. On August 26, 2004, Defendant released a press statement which refuted the FDA's analysis and restated Defendant's support for the cardiovascular safety of Vioxx.

126. Despite its defense of Vioxx, one month later, on September 30, 2004, Defendant recalled Vioxx from the market, after having to halt the APPROVe study (Adenomatous Polyp

Prevention on Vioxx). The study was underweighted to evaluate the use of Vioxx for recurrent colon polyps. The researchers found an alarming number of cardiovascular events among the drug users in the APPROVe study.

127. At the same time, Defendant was aware that the FDA, as of August 24, 2004, was advising Defendant to warn about the risk of osteonecrosis of the jaws for its Fosamax patients. Because Defendant knew that its blockbuster drug, Vioxx, was about to be pulled from the market, placing more importance on the $3 billion plus sales of Fosamax, Defendant deliberately chose not to amend its packaging and labels of Fosamax to include the risk of osteonecrosis of the jaws, fearing that such a warning would result in reduced revenues for its second largest income producer, Fosamax.

128. Defendant's acts were willful and malicious in that Defendant's conduct was carried on with a conscious disregard for the safety and rights of Plaintiff. Defendant's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendant in an amount appropriate to punish Defendant, and to deter similar conduct in the future.

V. DAMAGES

129. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth here and further alleges as follows:

130. As a proximate result of Defendant's acts and omissions, Plaintiff sustained and suffered oral and dental complications, including exposed bone.

131. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff sustained oral and dental complications and exposed bone. In addition, Plaintiff required and will continue to require dental and medical care and treatment.

Plaintiff has incurred and will continue to incur dental and medical and other related expenses. Plaintiff also suffered and will continue to suffer diminished capacity for the enjoyment of life, the diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, and activation of latent conditions and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

132. Additionally, Plaintiff has suffered or will suffer the following damages:

a. Physical pain and mental anguish in the past;

b. Physical pain and mental anguish in the future;

c. Disfigurement in the past and future;

d. Physical impairment in the past and future;

e. Loss of enjoyment of life and diminished physical abilities;

f. Pain and suffering;

g. Worry and anxiety;

h. Medical expenses in the past and future; and

i. All hedonic damages allowed by law.

133. As stated above, Defendant acted with intent and malice. Plaintiff is entitled to an award of exemplary damages.

VI. DEMAND FOR JURY TRIAL

134. Plaintiff requests a trial by jury on all counts.

VII. PRAYER

WHEREFORE, Plaintiff demands judgment against Defendant for:

a. Actual damages; and

b. Pre-judgment and post-judgment interest as allowed by law in an amount in excess of the jurisdictional limits of this court, plus costs, as well as other equitable and just relief. Additionally, Plaintiff demands judgment against Defendant for exemplary damages.

Dated this 30th day of April, 2008.

Respectfully submitted,

FLEMING & ASSOCIATES, L.L.P.

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